IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CHRISTOPHER NEWMAN, ET AL.	:	
	:	
v.	:	CIVIL NO. CCB-00-2609
	:	
MOTOROLA, INC., ET AL.	:	

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MEMORANDUM

Claiming that his use of a wireless handheld telephone manufactured by Motorola caused his brain cancer, Dr. Christopher Newman and his wife filed a multi-count complaint against numerous defendants in Baltimore City Circuit Court. The defendants removed the case to this court, asserting diversity jurisdiction because the one non-diverse defendant, Verizon Maryland, had been fraudulently joined. The plaintiffs' motion to remand the case to state court was denied on December 21, 2000. See Newman v. Motorola, Inc., 125 F.Supp.2d 717 (D. Md. 2000).[1] The parties were directed to begin discovery focused on the issues of both general and specific causation: that is, (1) can the use of wireless handheld telephones cause brain cancer, and (2) did the use of the Motorola phone cause Dr. Newman's cancer. After a substantial period of discovery and the designation of experts, both sides filed motions to exclude the other's proffered expert testimony. An evidentiary hearing was held from February 25 to March 1, 2002, and post-hearing correspondence has been received through September 10, 2002. Because no sufficiently reliable and relevant scientific evidence in support of either general or specific causation has been proffered by the plaintiffs, as explained below, the defendants' motion will be granted and the plaintiffs' motion will be denied.

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[1]By separate memorandum and order issued today, the plaintiffs' request to add another non-diverse defendant, Nationwide Motor Sales, has been denied.

When testimony concerning scientific, technical or other specialized knowledge is offered in support of a party's claim, the trial judge must ensure under Rule 702 of the Federal Rules of Evidence that any such testimony is "not only relevant, but reliable." Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589 (1993); see also Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147-49 (1999) (extending Daubert's analysis of expert testimony based on "scientific" knowledge to expert testimony based on "technical" and "other specialized" knowledge); Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001). As the Fourth Circuit has explained: "While Rule 702 was intended to liberalize the introduction of relevant expert evidence, courts must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to be both powerful and quite misleading." Cooper, 259 F.3d at 199 (quoting Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir. 1999) (quoting Daubert, 509 U.S. at 595)) (internal quotation marks omitted). Accordingly, in making the determination of admissibility under Rule 104(a) of the Federal Rules of Evidence, the judge must conduct "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Daubert, 509 U.S. at 592-93; Cooper, 259 F.3d at 199. The proponent of the testimony must establish its admissibility, although it need not prove its expert's theory is correct. Daubert, 509 U.S. at 592 n.10; Cooper, 259 F.3d at 199; Maryland Cas. Co. v. Therm-O-Disc, Inc., 137 F.3d 780, 783 (4th Cir. 1998).

In essence, the trial court must perform a two-pronged analysis in order to satisfy its gate-keeping function. The first question is whether proffered scientific evidence is valid and reliable. United States v. Barnette, 211 F.3d 803, 815 (4th Cir. 2000). The second question is whether it

will help the trier of fact, which is generally a question of relevance, or "fit:" assuming the evidence is reliable, does it apply to the facts in the individual case under consideration.[2] Id. at 815; Maryland Cas. Co., 137 F.3d at 784.

In Daubert, the Court identified several factors that may bear on the determination of admissibility of scientific evidence. These include:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper, 259 F.3d at 199, citing Daubert, 509 U.S. at 592-94; see also Ruffin v. Shaw Indus., Inc., 149 F.3d 294, 296 (4th Cir. 1998). This list is neither definitive nor exhaustive, however, and some factors may be more pertinent than others "depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." Cooper, 259 F.3d at 199-200; see also Kumho Tire, 526 U.S. at 150; Ruffin, 149 F.3d at 296; Maryland Cas. Co., 137 F.3d at 784-85 and n.29. A trial court's decision to admit or exclude expert testimony is reviewed for abuse of discretion. General Elec. Co. v. Joiner, 522 U.S. 136, 138-39 (1997); Cooper, 259 F.3d at 200.

With these principles in mind, I will turn to a discussion of cell phone safety generally, Dr. Newman's individual history, and the evidence offered by Dr. Newman to support his claim.

Wireless handheld telephones (alternatively referred to as cell phones) emit

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[2] Whether scientific or technical testimony will assist the trier of fact also depends on whether the topic of the proposed testimony is within the common knowledge of the jury. See United States v. Dorsey, 45 F.3d 809, 814-15 (4th Cir. 1995). In this case, scientific and technical information would be necessary to educate the jury.

radiofrequency radiation ("RFR"), a form of non-ionizing radiation located along the electromagnetic spectrum. American cell phone frequency is generally about 835 to 845 megahertz (Lai Tr. 2/25/02 at 157; DX 142, Davis Am. Expert Report at 6 n.3)[3]; European cell phones are at 900 megahertz (Lai Tr. 2/25/02 at 158), and microwave ovens, by comparison, operate at approximately 2450 megahertz. (Davis Tr. 3/1/02 at 878; Lai Tr. 2/25/02 at 156; DX 129). The standard measure for exposure to radiofrequency radiation from a wireless phone is specific absorption rate ("SAR"), which is expressed in watts per kilogram. The potential for adverse health effects from exposure to radiofrequency radiation has been the subject of scientific discussion for many years. It is also a matter of governmental concern, particularly as the number of cell phone users expands. The Federal Communications Commission ("FCC"), which has been vested by Congress with extensive authority to regulate and set standards for wireless telecommunications, has promulgated regulations setting an SAR that wireless phones may not exceed. 47 C.F.R. § 2.1093(d)(2) (2002). In doing so, it relied on a "consensus view of the federal agencies responsible for matters relating to the public safety and health," including the Environmental Protection Agency ("EPA"), Food and Drug Administration ("FDA"), and Occupational Safety and Health Administration ("OSHA"). *In re Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation*, 11 F.C.C.R. 15123 (1996); (see also Defs.' Mot. to Exclude Pls.' Expert Witness Test. at Ex. 18, 19).

Because of the national and international scientific interest in radiofrequency radiation, there is a substantial body of literature to consult in order to determine whether the plaintiffs'

[3] "DX" references are to the defendants' hearing exhibits; "PX" refers to plaintiffs' hearing exhibits.

theory and technique of demonstrating cancer causation has attained general acceptance in the scientific community. The short answer is that no such general acceptance has been shown.[4] As more fully discussed below, several published epidemiological studies have found no scientifically reliable basis to conclude that the use of wireless handheld phones causes brain cancer. See Peter D. Inskip, et al., *Cellular-Telephone Use and Brain Tumors*, NEW ENG. J. MED. 344:79-86 (2001) (DX 89) ("Our results do not substantiate the concern that some brain tumors diagnosed in the United States during the mid-1990s were caused by the use of handheld cellular telephones. There was little or no indication of an increased risk of glioma, meningioma, or acoustic neuroma associated with any use, cumulative use, or the laterality of use of these telephones."); Christoffer Johansen, et al., *Cellular Telephones and Cancer - a Nationwide Cohort Study in Denmark*, J. NAT'L CANCER INST. 93:203-207 (2001) (Defs.' Mot. to Exclude Pls.' Expert Witness Test. at Ex. 41) ("The results of this investigation, the first nationwide cancer incidence study of cellular phone users, do not support the hypothesis of an association between use of these telephones and tumors of the brain or salivary gland, leukemia, or other cancers."); Joshua E. Muscat, et al., *Handheld Cellular Telephone Use and Risk of Brain Cancer*, JAMA 284:3001-3007 (2000) (DX 88) ("The use of handheld cellular telephones was unrelated to the risk of brain cancer in the current study."); Kenneth J. Rothman, et al., *Overall Mortality of Cellular Telephone Customers*, EPIDEMIOLOGY, 7:303-305 (1996) (Defs.' Mot. to Exclude Pls.'

[4] Admissibility does not depend on the number of experts who agree with a particular conclusion. The validity and reliability of the technique and methods underlying the plaintiffs' proffered expert opinions are the issues to be determined. As the Supreme Court has recognized, however, "conclusions and methodology are not entirely distinct from one another. . . . A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." Joiner, 522 U.S. at 146; see also Cooper, 259 F.3d at 202.

Expert Witness Test. at Ex. 68).[5] In addition to these epidemiologic studies, and the consensus expressed by the FCC, the defendants have proffered reports from numerous international organizations,[6] finding no reliable evidence of cancer causation from exposure to wireless handheld phones.

The plaintiffs have proffered a number of experts from different scientific disciplines to support their theory of causation.[7] The defendants in turn support their motion to exclude with an array of distinguished clinical, academic, and research scientists from the same relevant disciplines.[8] Crucial to the plaintiffs' case, however, is their proffered expert in the field of epidemiology and oncology, Dr. Lennart Hardell. Expert witnesses on both sides of the case

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[5] Appropriately, the authors of these studies also caution about the limits of their conclusions. (Stampfer Tr. 2/28/02 at 833, 836-37). The Muscat authors concluded: "Our data suggest that use of handheld cellular telephones is not associated with risk of brain cancer, but further studies are needed to account for longer induction periods, especially for slow-growing tumors with neuronal features." (DX 88). Inskip stated: "These data do not support the hypothesis that the recent use of hand-held cellular telephones causes brain tumors, but they are not sufficient to evaluate the risks among long-term, heavy users and for potentially long induction periods." (DX 89).

[6] These include The World Health Organization (2000) (Defs.' Mot. to Exclude Pls.' Expert Test. at Ex. 79); Health Canada (2001) (Id., Ex. 35); British Medical Association (2001) (Id., Ex. 5); Health Council of the Netherlands (2001) (Id., Ex. 36); European Commission (Id., Ex. 17); Independent Expert Group on Mobile Phones, U.K. (2000) (Id., Ex. 37).

[7] Dr. Neil Cherry, for example, who was offered only to provide background testimony in the field of radiofrequency radiation, holds a doctoral degree in atmospheric physics and has special expertise in the field of meteorology. (Cherry Tr. 2/25/02 at 123-24; PX 5, 19A). The objectivity of his testimony was called into serious question. (See Cherry Tr. 2/25/02 at 130-34). In any event, his testimony was largely irrelevant to the issue of causation.

[8] I have considered the affidavits of all of the plaintiffs' and defendants' proffered experts even if those experts were not called to testify at the hearing. Similarly, I have considered, but not necessarily mentioned in this memorandum, all the scientific studies introduced by both sides.

agreed that animal studies are insufficient, and there must be reliable epidemiological evidence of a link between cell phones and cancer to support a theory of cancer causation in humans. (Hardell Tr. 2/28/02 at 642; Phillips Tr. 2/27/02 at 529-30; Richter Tr. 2/26/02 at 356-57; Laterra Tr. 3/1/02 at 1013-15, 1019; Stampfer Tr. 2/28/02 at 798-99). While relevant animal studies and an understanding of the scientific principles involved in radiofrequency emissions contribute to the debate, they are not in isolation sufficient to permit the conclusion that the use of cell phones caused Dr. Newman's or any other human cancer. See Joiner, 522 U.S. at 144; Raynor v. Merrell Pharm. Inc., 104 F.3d 1371, 1375-76 (D.C. Cir. 1997). For that reason, I will focus first on the testimony offered by Dr. Hardell.

Dr. Hardell is the only medical doctor relied on by the plaintiffs to support specific causation.[9] He is a full professor in oncology at the University Hospital in Orebro, Sweden, who divides his time among research, teaching, and clinical practice. (Hardell Tr. 2/28/02 at 621-23). He has diagnosed and treated "thousands" of cancer patients and "hundreds" of brain cancer patients since he began work as an oncologist in 1976. (Id. at 624-25.) Dr. Hardell also has conducted and published numerous studies in the field of cancer epidemiology. (Id. at 625; see PX 6, Hardell Aff. at ¶ 9). His education, experience, and training, considered by themselves, establish his qualifications to provide opinion testimony in the fields of oncology and epidemiology, if those opinions otherwise satisfy the Daubert standards.

In preparation for offering causation opinions in this case, Dr. Hardell interviewed Dr.

[9] Dr. Elihu Richter, a specialist in preventive medicine and epidemiology, is offered to support only general causation. Dr. Jerry Phillips, a biochemist with expertise in the biological effect of electromagnetic radiation, is offered to support both general and specific causation, but has no medical degree.

Newman by phone and reviewed Dr. Newman's medical records and MRI's. (Hardell Tr. 2/28/02 at 627-29, 632; PX 182-A, 188). He concluded that the tumor type was "anaplastic astrocytoma Grade 3," and that "the location of the tumor was right side of the brain in the occipital area extending into the temporal area." (Hardell Tr. 2/28/02 at 630).[10] He assumed, based on information from Dr. Newman and his counsel, that Dr. Newman used an analog mobile phone from October 1992 until the diagnosis of his brain tumor in March 1998. From October 1992 through April 1995, Dr. Newman used the phone approximately thirty minutes per month; from May 1995 until May 1998 the phone bills showed usage of 19,684 minutes. Thus the total amounted to 343 hours of cell phone use.[11] Dr. Newman primarily held the phone in his right hand next to his right ear with the antenna not extended. (Id. at 633-35). Dr. Hardell

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[10] Dr. Hardell's testimony concerning the location of the tumor is challenged by one of the defense experts. According to John Laterra, M.D., Ph.D., a clinical neuro-oncologist and molecular biologist who is an associate professor at the Johns Hopkins University School of Medicine and director of the neuro-oncology research laboratory at Johns Hopkins Hospital and the Kennedy Krieger Institute (DX 350, Laterra Aff.), the MRI scans and surgical report show that the tumor was in the occipital lobe, with no significant temporal lobe involvement. (Laterra Tr. 3/1/02 at 1001-1004). This is significant to the extent that Dr. Hardell's theory of causation relies on maximum RFR exposure occurring at the particular location where the phone was held by Dr. Newman. Dr. Laterra also explained that Dr. Newman's tumor was located "deeper" in the brain than many other common tumors. The outer margin of the tumor was three centimeters removed from the nearest edge of the skull (DX 147); it was not on the surface of the brain, or the part of the brain nearest the scalp. (Laterra Tr. 3/1/02 at 1005-06). According to Dr. Christopher Davis, professor of electrical and computer engineering at the University of Maryland (DX 138, 140; Defs.' Mot. to Exclude Pls.' Expert Witness Test. at Ex. 12), "the skull is a shield for electromagnetic radiation" and thus at three centimeters in, the maximum SAR is significantly reduced. (Davis Tr. 3/1/02 at 906-07). He concluded, therefore, that "Dr. Newman's highest exposure from his cell phone is not in the location where his tumor is." (Id.).

[11] Dr. Laterra believes that Dr. Newman's report of a left sided visual field cut approximately eighteen months prior to his diagnosis in March 1998 indicates that the tumor was present to some degree as early as September 1996, when Dr. Newman had only been using a cell phone for 166 hours. (Laterra Tr. 3/1/02 at 998-1002). In Dr. Laterra's opinion, Dr. Newman's cell phone use had nothing to do with his tumor. (Id. at 1010-11).

concluded that the tumor was in the area closest to where the antenna was held, the "right temporal occipital area" of the brain. (Id. at 636).

To support his opinion that the use of an analog cellular phone caused Dr. Newman's brain tumor, Dr. Hardell relied on the results of his own epidemiological research. Prior to the hearing, Dr. Hardell had published in peer-reviewed journals two relevant papers: *Use of cellular telephones and the risk for brain tumours: A case-control study,* INT'L J. OF ONCOLOGY 15: 113-116 (1999) (the "1999 Paper") (PX 41) and *Ionizing radiation, cellular telephones and the risk for brain tumours,* EUR. J. OF CANCER PREVENTION 10:523-529 (2001) (the "2001 Paper") (PX 37). Both are based on a study group of 233 patients with a diagnosis of brain tumor.[12] In the 1999 Paper, Dr. Hardell reported no "overall increased risk for brain tumours associated with exposure to cellular phones," whether analog or digital, and "no dose-response effect" (PX 41).[13] A "non-significantly" increased risk for brain tumors located on the same side of the head as the cell phone use ("ipsilateral") was found, but "the results were based on low numbers and must be interpreted with caution." (Id.). By recalculating the data combining right and left sided tumors in the 2001 Paper, a method apparently rejected in the 1999 Paper (see Stampfer Tr. 2/28/02 at 814), Dr. Hardell found an increased risk with ipsilateral use of a mobile phone, based on only thirteen exposed cases. (PX 37).

Dr. Hardell undertook a second study with a larger group of cases obtained from

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[12] The study ultimately encompassed 209 cases and 425 controls. (PX 37, 41).

[13] Dose-response is important as an indication of causality. (Stampfer Tr. 2/28/02 at 821). A dose-response relationship exists when "the more intense the exposure, the greater the risk of disease." REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 377 (Federal Judicial Center, ed., 2000).

Sweden's regional cancer center registries. Questionnaires were sent to approximately 1,600 cases[14] and the same number of controls, with responses obtained from 1,429 of the cases and 1,470 of the controls. (PX 42, 43).[15] The data was gathered in 2001 and summarized in two papers: "Cellular and cordless telephones and the risk for brain tumors" (PX 42) and "Use of cellular telephones and the risk for astrocytoma" (PX 43). The first paper (PX 42) included results for benign as well as malignant brain tumors. Dr. Hardell found an increased risk (odds ratio 1.26) of developing a brain tumor with use of an analog phone for more than one year up to six years. (Hardell Tr. 2/28/02 at 670-71). That overall odds ratio was reached, however, only by including acoustic neurinomas, a benign type of tumor excluded from his 1999 Paper, where the results showed no significant increase. (PX 41, 42; Defs.' Mot. to Exclude Pls.' Expert Witness Test. at Ex. 73, Stampfer Decl. at ¶¶ 80-81.) Importantly, Dr. Hardell's first paper (PX 42) found no statistically significant increased risk for development of malignant brain tumors with mobile phone use. (PX 42; Defs.' Mot. to Exclude Pls.' Expert Witness Test. at Ex. 73, Stampfer Decl. at ¶ 82).

In his second paper resulting from the larger study, Dr. Hardell looked at risk findings associated with development of malignant brain tumors in 588 of the cases. Overall no statistically significant increased risk was shown for development of any malignant brain tumor, including astrocytoma. (PX 43).

Dr. Hardell supports his theory of causation, however, with his purported findings of an

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[14] "Cases" refers to persons diagnosed with brain tumor; "controls" were persons without a tumor diagnosis. Both groups had used mobile phones. (PX 42, 43).

[15] Versions of the papers with page numbers also were submitted at the hearing as PX 42A and 43A.

increased association between development of malignant brain tumors, including astrocytoma, and "ipsilateral" phone use: that is, persons who developed tumors were more likely to report that their phone use had been on the same side of the head as the tumors. (PX 42, 43; Hardell Tr. 2/28/02 at 669-76). The validity and relevance of this finding is subject to serious criticism, as more fully discussed below.[16]

Applying the Daubert factors, it is first important to note that neither of these papers had been accepted for publication in a peer-reviewed journal as of the time of the hearing in February 2002. Indeed, the manuscript was rejected for publication by *The Lancet*, a well-respected British medical journal, based on substantial criticism by the peer reviewers, including concerns about the "large confidence intervals" and that "the overall message of the paper was written much too forcefully." (DX 158, 171).[17] Dr. Hardell withdrew his request for publication in *Oncology Research.* (DX 159; Hardell Tr. 2/28/02 at 702-03).

Subsequent to the hearing, Dr. Hardell's second paper, "Use of cellular telephones and the risk for astrocytoma," was accepted by *The International Journal of Radiation Biology*, a peer-reviewed journal, although it has not yet been published. (Letter from H. Russell Smouse,

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[16] It is interesting that the Muscat study, while not suggesting a causal association, found that in the cases with temporal lobe cancer a greater proportion of tumors occurred in the contralateral, i.e., opposite, rather than the ipsilateral side of the head. (DX 88). The number of such cases, admittedly, was relatively small.

[17] These comments are taken from the correspondence between Dr. Hardell and the journal editors. The peer review comments themselves, whose authors are anonymous as part of the confidential peer review process, remain sealed and will be given little substantive weight, other than to note that their collective effect was to preclude publication of Dr. Hardell's articles in *The Lancet*. As discussed and for the reasons stated on the record at the hearing, all motions to seal were denied except as to the peer review comments themselves. (See Tr. 2/26/02 at 309; Tr. 2/27/02 at 605-11).

Esq. to Court of 5/29/02, attachment). In his letter to Dr. Hardell, however, the editor noted that "never before have we accepted a paper in the face of such low scores by referees." (Id.) Dr. Hardell's first paper, "Cellular and cordless telephones and the risk for brain tumours," was accepted by the *European Journal of Cancer Prevention* and published in volume 11 (2002).[18] (Letter from H. Russell Smouse, Esq. to Court of 8/12/02, attachment; see also Lennart Hardell, et al., *Cellular and cordless telephones and the risk for brain tumours,* EUR. J. OF CANCER PREVENTION 11:377-386 (2002)).

The fact of publication, of course, does not eliminate the need to examine the results and methodology of the study, keeping the inquiry focused on relevance and validity as it relates to the causation opinions offered in this case. On the issue of relevance, as noted, neither paper shows any statistically significant increased risk for the development of malignant brain tumors based on analog cell phone use. The plaintiffs rely instead on the increased risk for all brain tumors, obtained by including the category of benign acoustic neuroma, which is not applicable to Dr. Newman's case and was not observed in Dr. Hardell's 1999 Paper. They also rely on the association of astrocytoma with ipsilateral use. The validity of these results is suspect for several reasons.

First is the problem of recall bias. Dr. Hardell's questionnaire necessarily relied on persons who had developed a brain tumor on one side of their head being asked to recall on which side of the head they had used their cell phones.[19] Dr. Meir Stampfer, professor of

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[18] The editor's letter to Dr. Hardell of March 28, 2002, indicates that the manuscript was being accepted after comments were received from only two reviewers "as the third referee has still not responded." (Letter from H. Russell Smouse, Esq. to Court of 4/2/02, attachment).

[19] Possible responses were limited to right, left, or (later) equal, with no "variable" option.

medicine at Harvard Medical School and Chair of the Department of Epidemiology at the Harvard School of Public Health (Defs.' Mot. to Exclude Pls.' Expert Witness Test. at Ex. 73), persuasively stated the reasons for finding that recall bias likely had affected Dr. Hardell's results.[20] One of the most significant of those reasons was that the study found an increased risk of tumor with ipsilateral use for all phones -- analog, digital and cordless -- even though there is otherwise no scientific claim that cordless phones cause brain cancer. (Stampfer Tr. 2/28/02 at 819-20; Hardell Tr. 3/1/02 at 986-90). Another is the pattern of decreased risk on the contralateral side, averaging out to an overall "null" finding (no association). (Stampfer Tr. 2/28/02 at 819).

Second is the lack of any demonstrated dose-response relationship, which Dr. Hardell agrees is one of the most important factors to prove causality. (Hardell Tr. 2/28/02 at 722). Fairly read, his papers, deposition and hearing testimony do not support finding a scientifically valid dose-response relationship for mobile phone use and brain cancer, particularly not for astrocytoma. (See Defs.' Mem. in Supp. of their Mot. to Exclude Pls.' Expert Witness Test. at 43-44; Hardell Dep. 513:9-515:10, 555:4-12, 502:5-13, 499:3-8; Hardell Tr. 2/28/02 at 722-27; Stampfer Tr. 2/28/02 at 806, 821).

Third are the significant problems with relying on an ipsilateral association as evidence of causation when there is no underlying evidence of an association between cell phone use and development of malignant brain tumors. As explained by a review in *The Lancet* commenting on Dr. Hardell's 1999 Paper, his ipsilaterality theory is inherently flawed: "[S]ince there had been

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[20] See Stampfer Tr. 2/28/02 at 816-820; Defs.' Mot. to Exclude Pls.' Expert Witness Test. at Ex. 73, Stampfer Decl. at ¶¶ 85-89; cf. Richter Tr. 2/26/02 at 323 (unable to refute or endorse Dr. Stampfer's position that there is a strong recall bias in Dr. Hardell's study).

no increase in the overall risk of tumour, an association between side of tumour and side of telephone use requires the implausible inference that telephone use does not affect the risk of whether a brain tumour will occur but only its location." (See Defs.' Mem. in Supp. of their Mot. to Exclude Pls.' Expert Witness Test. at 37, quoting Kenneth J. Rothman, *Epidemiological evidence on health risks of cellular telephones*, THE LANCET, 356:1837-1840 (2000)). That criticism is particularly applicable as to the papers resulting from Dr. Hardell's later studies, where the numbers involved were sufficiently large to show an increased risk for malignant brain tumors if such risk existed. (Cf. Hardell Dep. at 365:17 - 368:19).

Fourth, Dr. Hardell puts overdue emphasis on the positive findings for isolated subgroups of tumors. As Dr. Stampfer explained, it is not good scientific methodology to highlight certain elevated subgroups as significant findings without having earlier enunciated a hypothesis to look for or explain particular patterns, such as dose-response effect. In addition, when there is a high number of subgroup comparisons, at least some will show a statistical significance by chance alone. In Dr. Hardell's study, there is no overall showing of increase in a significant number of the subgroups. (See Stampfer Tr. 2/28/02 at 807-10). While Dr. Richter disagrees with this analysis (Richter Tr. 2/26/02 at 321-22), I find Dr. Stampfer more persuasive.

Dr. Hardell's methodology for testing laterality has not been used by any other scientist proffered to the court (See Defs.' Mem. in Supp. of their Mot. to Exclude Pls.' Expert Witness Test. at 38; Hardell Dep. 426:2-12). Nor has it been replicated. The Inskip and Muscat studies, which tested laterality by other means and admittedly with a smaller number of people, do not show increased risk. (Stampfer Tr. 2/28/02 at 815-16; Richter Tr. 2/26/02 at 306-07; DX 89; DX

88).[21] Part of the difficulty is that Dr. Hardell, of necessity, assigned a "phantom" tumor to a particular side of the head in the control group and did so using the same side of the head as the matched case. This procedure appears inconsistent with the epidemiological principle that exposure cannot be defined on the basis of outcome. (Stampfer Tr. 2/28/02 at 812-14; Richter Tr. 2/26/02 at 323-24; Defs.' Mot. to Exclude Pls.' Expert Witness Test. at Ex. 73, Stampfer Decl. ¶ 90).

Arrayed against Dr. Hardell's findings are the numerous studies published in peer-reviewed journals and by international scientific and governmental bodies already referred to. Dr. Eugenia Calle, the director of analytic epidemiology for the American Cancer Society (Calle Tr. 2/28/02 at 841-42), reviewed the results of the Muscat, Inskip, and Johansen studies, as well as Dr. Hardell's 1999 and 2001 Papers,[22] and noted the consistency of their results with the reports of more than ten scientific panels and government bodies showing no causal association between the use of cell phones and the development of brain cancer. (See Defs.' Mot. to Exclude Pls.' Expert Witness Test. at Ex. 5, 17-20, 35-36, 67, 79; Calle Tr. 2/28/02 at 844-849). She found "no reliable basis" for any association between cell phone use and brain cancer. (Calle Tr. 2/28/02 at 848-49). Also significant are the national incidence data for brain tumors. Tumors of the type diagnosed in Dr. Newman have been recognized to be in existence for close to a hundred years, with most having no known cause. (Laterra Tr. 3/1/02 at 1010-1011; see also Phillips Tr.

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[21] The Finnish study cited by Dr. Hardell, Annssi Auvinen, et al., *Brain Tumors and Salivary Gland Cancers Among Cellular Telephone Users*, EPIDEMIOLOGY 13:356-359 (2002), did not address laterality. It found only a "weak" association between gliomas and analog cellular phones and indicated that further studies were necessary "for valid risk assessment."

[22] His 2002 papers had not yet been published.

2/27/02 at 534-35). There have been variations, but no significant overall change, in the incidence of such tumors despite the increasing use of cell phones among the American population. As Dr. Stampfer and Dr. Laterra both testified, nationally maintained data (the Surveillance, Epidemiology, and End Results ("SEER") registry developed by the National Cancer Institute) showed no scientifically significant change in the reporting of all gliomas for 35 to 39 year olds (Dr. Newman's age group) in the ten-year period 1988 to 1998 or for malignant brain tumors among 35 to 39 year olds from 1973 to 1998, as well as other age groups. (Stampfer Tr. 2/28/02 at 794, 797-98; Laterra Tr. 3/1/02 at 1010-1012; DX 236, 353-354).[23] Dr. Laterra, like Dr. Stampfer, found no scientific evidence that would implicate cell phone use in regard to brain tumors. (Laterra Tr. 3/1/02 at 1011; Stampfer Tr. 2/28/02 at 800).

The plaintiffs offer Dr. Elihu Richter, senior lecturer and head of the unit of occupational and environmental medicine unit at Hebrew University, to testify in the field of epidemiology. He earned a medical degree from New York University in 1963 and a Master's in Public Health from Harvard University in 1966. (Richter Tr. 2/26/02 at 263-64; Pls.' Opp. to Defs.' Mot. to Exclude Pls.' Expert Witness Test. at Ex. 88). His opinion that exposure to radiofrequency radiation from cellular telephones can cause brain cancer in humans relies in significant part on Dr. Hardell's later study and on certain animal studies, including those by plaintiffs' expert Henry Lai, Ph.D., on the effect of radiofrequency radiation on DNA. (Richter Tr. 2/26/02 at 297-98).

Dr. Richter, who was asked on June 6, 2001 to become an expert witness for the

[23] According to Inskip, handheld cellular telephones were introduced to the U.S. market in 1984, although they were not widely used until the mid-1990s. (DX 89).

plaintiffs, submitted his initial report on June 8, 2001, without the benefit of significant information about Dr. Newman's particular cell phone use. (DX 82-84). At his deposition in August 2001, he was under the mistaken impression that Dr. Newman had used the handheld cell phone for 42,000 minutes from 1995 to 1999. (Richter Tr. 2/26/02 at 336). Accordingly, his opinion on specific causation was withdrawn before the hearing. (Id. at 338-39). Additionally, Dr. Richter conceded that Dr. Newman's actual duration of use falls within that of the results reported in the Muscat and Inskip studies (Id. at 350, 354), where no increased risk was found. (See also Stampfer Tr. 2/28/02 at 801-02, 805).

The plaintiffs' experts relied on a number of animal studies which they believe showed relevant biological effects of radiofrequency radiation. No peer-reviewed published study was identified, however, that reported an increased risk of brain cancer from RFR at cell phone frequencies. (Richter Tr. 2/26/02 at 356; Phillips Tr. 2/27/02 at 559-60). Plaintiffs' expert Dr. Jerry Phillips, who holds a Ph.D. in biochemistry, has done significant research on the biological effects of electromagnetic radiation and is presently employed by the Biological Sciences Curriculum Study in Colorado. (Phillips Tr. 2/27/02 at 409-16; PX 84-A). He offered the following opinion on general causation: "Based on my reading of the bioelectromagnetic literature and my reading of the larger body of science, RFR exposure can produce biological effects that may lead to cancer development." (Phillips Tr. 2/27/02 at 523; see also PX 84-B; Pls.' Opp. to Defs.' Mot. to Exclude Pls.' Expert Witness Test. at Ex. 8). In itself this is hardly sufficient to support an opinion that the use of cellular phones can cause brain cancer in

humans.[24] He gave his opinion without relying on epidemiological studies (Phillips Tr. 2/27/02 at 528), although he agrees that epidemiology is necessary to classify RFR as a human carcinogen. (Id. at 529-30).

Dr. Phillips and, as noted, Dr. Richter relied in part on three studies published by Dr. Henry Lai, who holds a Ph.D. in psychology and is presently a "life scientist in the field of bioelectromagnetics" at the University of Washington Department of Bioengineering. (Lai Tr. 2/25/02 at 150). He has taught and been involved with research in that field, including the effects of RFR, for over twenty years, and has served on standard-setting committees. (Id. at 148-150; PX 4, 52A). Dr. Lai conducted studies in which he exposed rats to RFR at 2450 megahertz, then anesthetized and decapitated them, and by the Singh "comet assay" method found an increased amount of DNA single strand and double strand breaks. (Lai Tr. 2/25/02 at 173-76; PX 53, 54, 56). Single strand DNA breaks are extremely common and are readily repaired by the body's own process; double strand breaks are more difficult to repair. (Lai Tr. 2/25/02 at 161-62; Israel Tr. 3/1/02 at 943-44).[25] DNA damage can result in a mutation which gives rise to a cancer cell,

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[24] Dr. Phillips also offered a specific opinion that RFR exposure caused Dr. Newman's tumor. (Phillips Tr. 2/27/02 at 523-24). Given his lack of a medical degree, the fact that he has never diagnosed a patient with cancer, and the fact that the only context in which he has ever given an opinion on cancer causation is that of cell phone litigation (Id. at 525-526), this opinion is well outside of his field of expertise. His willingness to proffer such an opinion affects the credibility of his general causation opinion.

[25] Dr. Lai agreed with defense expert Dr. Davis that the RFR at cell phone levels (as compared to ionizing radiation such as x-rays) is not a strong enough energy source to break chemical bonds and thereby cause DNA damage. (Lai Tr. 2/25/02 at 158, 174-75; Davis Tr. 3/1/02 at 875, 888, 897). Dr. Davis, in discussing the studies that report biological effects at RFR levels, stated that "the vast majority of physical scientists just accept that it's implausible for low-end photons at low powers to cause any of these effects." (Davis Tr. 3/1/02 at 898-99). Dr. Lai theorized that RFR caused an increase in "free radical formation" in cells, which led to DNA strand breakage as an "indirect" effect. (Lai Tr. 2/25/02 at 175). Where, as here, no

although this "rarely" occurs. (Israel Tr. 3/1/02 at 944-45; Lai Tr. 2/25/02 at 162; cf. Phillips Tr. 2/27/02 at 432-34, 546).

The most substantial problem with the Lai studies, which were published in peer-reviewed journals, is one of relevance or "fit." They were conducted at 2450 megahertz, a significantly higher frequency than the range at issue in this case. Dr. Newman's cell phone frequency ranged from 824 to 848 megahertz (Lai Tr. 2/25/02 at 227); American cell phones generally are at 835 megahertz (Id. at 157-58); European cell phones are at 900 megahertz (Id. at 158-59). Dr. Lai himself participated in an unpublished 1999 Wireless Telephone Research ("WTR") study involving exposure of rats using an analog signal at 837 megahertz directly to the head which showed no positive result for rat brain DNA damage. (Lai Tr. 2/26/02 at 202-206, 212-13, 217-18, 221; DX 28; Israel Tr. 3/1/02 at 952). His published studies have not been replicated by other scientists (neither precisely duplicated nor validated by similar studies). (See Lai Tr. 2/25/02 at 181-84; Israel Tr. 3/1/02 at 948-49, 978-79; PX 59, 60, 161).[26] Dr. Lai, who did not offer a causation opinion (Lai Tr. 2/26/02 at 230), stated in a 1998 paper presented after he had completed the three rat brain studies noted above that "insufficient research data are available to conclude whether exposure to RFR during the normal use of mobile telephones could lead to any hazardous health effects." (Id. at 234). In a 1999 report to the Massachusetts

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plausible causal mechanism has been clearly established, valid and reliable epidemiological studies are of even greater importance.

[26] In the Malyapa studies (PX 59, 60, 161), an attempt was made to replicate Dr. Lai's studies involving exposure of rats to RFR at 2450 megahertz (2.45 gigahertz). It was not an exact duplication because the Olive assay method was used rather than the Singh method, two of the studies were in vitro rather than in vivo, and the rats in the whole animal study were asphyxiated rather than anesthetized before decapitation. (Lai Tr. 2/25/02 at 185-91). No increase in DNA strand breaks was reported. (Lai Tr. 2/26/02 at 252).

Department of Public Health, Dr. Lai and others stated that of the 7,000 to 10,000 scientific reports on the biological effects of RFR, the "overwhelming majority report no harmful effects providing the exposures remain at or below an SAR value of 4 watts per kilogram." (Id. at 236-38; DX 27).[27] As recently as his deposition in August 2001, he agreed that no statistical link had been established between radiofrequency radiation and human cancer. (Lai Tr. 2/26/02 at 259).

Dr. Mark Israel, called as a defense expert, is an oncologist and molecular biologist with extensive experience in research on the cause of brain tumors. He has worked at the National Institutes of Health and the Brain Tumor Research Center at the University of California in San Francisco, doing both in vivo and in vitro research, and is currently director of the Comprehensive Cancer Center at Dartmouth Medical Center, where much of the research focuses on astrocytomas and DNA. (Israel Tr. 3/1/02 at 930-33; Defs.' Mot. to Exclude Pls.' Expert Witness Test. at 39). He has over two hundred peer-reviewed publications and recently won the Farber Award for research related to brain tumors. (Israel Tr. 3/1/02 at 937). In reviewing the studies that report RFR effects on DNA, he found no "consistent body of information or line of investigation that provided me with any concern that alterations in DNA occurred as a result of RFR exposure." (Id. at 947). While there are some studies that claim effects, out of the large number of studies that have been done, they represent "a certain amount of scatter" around the null point. (Id.). Dr. Israel specifically criticized Dr. Lai's DNA studies for inadequacies in methodology and the lack of replication or other validation. (Id. at 948-55). His review of the whole animal studies led him to conclude that "there is no credible basis in the scientific

[27] The maximum SAR value for Dr. Newman's cell phone was 1.1 watts per kilogram (Lai Tr. 2/26/02 at 239-40); the FCC standard is 1.6. (Davis Tr. 3/1/02 at 910).

literature suggesting that RFR can cause brain tumors in animals." (Id. at 960).

The plaintiffs' primary argument to exclude the defense experts (particularly Dr. Stampfer and Dr. Israel) focuses on those experts' lack of specific experience in the field of radiofrequency radiation. The testimony proffered, however, is well within those witnesses' area of competence. As illustrated by Dr. Stampfer's frequent review and evaluation of grant proposals, general epidemiological principles can be applied to the analysis of studies performed in different substantive areas without first acquiring extensive experience in each of those subjects. Relevant to this case, for example, is the choice of Dr. Stampfer to chair a National Institutes of Health review panel for cancer grants. (See Stampfer Tr. 2/28/02 at 832-33). Similarly, Dr. Israel is more than competent to review in vitro and in vivo studies of the biological effects on cells of various potential cancer-causing agents, including RFR.[28]

In summary, the causation opinions proffered by the plaintiffs' experts do not pass the Daubert test. Their reasoning, theories, and methodology have not gained general acceptance in the scientific community, as demonstrated by the numerous national and international scientific and governmental published reports finding no sufficient proof that use of handheld cellular phones causes human brain cancer, and by the array of established, experienced, and highly-credentialed experts called to testify by the defense. The only published peer-reviewed epidemiological study finding such causation has serious flaws, and reliable epidemiology is essential before any link between animal studies and human cancer causation can be made.

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[28] Dr. Israel, with a lengthy and distinguished history of studying the molecular basis for the development of cancer, has not ignored RFR. Rather, as a matter of focusing energy and research funding, he has "seen nothing in my review of this field that suggests to me that this is a fruitful area for prioritizing research." (Israel Tr. 3/1/02 at 977-80).

Neither Dr. Hardell's work nor Dr. Lai's animal studies, heavily relied on by the plaintiffs' experts, have been replicated or otherwise validated by other scientists. Further, Dr. Lai's published studies lack relevance, or "fit," when applied to RFR at cell phone frequency.

For all the above reasons, the defendants' motion to exclude the testimony of plaintiffs' proposed experts will be granted, and the plaintiffs' corresponding motion to exclude the testimony of the defendants' experts will be denied. A separate Order follows.

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Date

_____
Catherine C. Blake
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CHRISTOPHER NEWMAN, ET AL.	:	
	:	
v.	:	CIVIL NO. CCB-00-2609
	:	
MOTOROLA, INC., ET AL.	:	

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ORDER

For the reasons stated in the accompanying Memorandum, it is hereby **ORDERED** that:

1. The parties' motions to seal (docket nos. 116-1, 117-1, 121 and 122) are **Denied**, except as to the confidential peer review comments;

2. The defendants' motion to exclude plaintiffs' expert witness testimony (docket no. 116-2) is **Granted**;

3. The plaintiffs' motion to limit and/or exclude the testimony of certain defense experts (docket no. 117-2) is **Denied**; and

4. The Clerk shall send copies of this Order and the accompanying Memorandum to counsel of record.

_____ _____

Date

Catherine C. Blake
United States District Judge